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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09.884.715	06.19.2001	Malcolm Richard Boyd	4-31830B	3629

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EXAMINER

MOSHER, MARY

ART UNIT PAPER NUMBER

1648

DATE MAILED: 09/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/884,715

Applicant(s)

BOYD, MALCOLM RICHARD

Examiner

Mary E. Mosher, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 6/19/2001, 10/12/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 7-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 7-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/117,154.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 6) ☐ Other: _____

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(a-d) as follows:

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Great Britain on 26 January 1996. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since the United States application 09/117,154 was filed more than twelve months thereafter. Applicant did not include a specific reference to PCT/GB97/00226 in the first paragraph of the specification within four months of the filing date for this application; the failure to do so is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to PCT/GB97/00226. See 37 CFR 1.78(a)(2)(i-ii). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

In the interest of compact prosecution, the examiner assumes that applicant will successfully petition for an amended priority claim. For the purposes of this Office action only, this application will be treated as if it obtained benefit of PCT/GB97/00226 and GB 9601544.1. However, this treatment does not relieve applicant of the burden of filing the petition and amending the specification to include a specific reference to PCT/GB97/00226.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Field et al (Antimicrobial Agents and Chemotherapy 39:11114-11119, 1995 or Antiviral Chemistry & Chemotherapy 6:210-216, 1995). Field teaches a method of treatment of herpes simplex virus infection in an animal, which comprises separately administering effective amounts of famcyclovir and cyclosporin, A, thereby meeting each and every claim limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-15 and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Harrell et al (Drug metabolism and disposition- the biological fate of chemicals 21:18-23, 1993, abstract only cited) and Field et al (Antimicrobial Agents and Chemotherapy 39:1114-1119, 1995 or Antiviral Chemistry & Chemotherapy 6:210-216, 1995). Harrell suggests coadministration of famciclovir and cyclosporin A for combating herpes viral infections in humans after organ or bone marrow transplants. Harrell teaches that famciclovir and penciclovir do not affect a human enzyme which acts on cyclosporin A. Field teaches that the combination of acyclovir and famciclovir was effective for both immunosuppression and HSV control in a mouse model. Therefore, it would have been within the ordinary skill of the art to administer both an immunosuppressant, such as cyclosporin A, and famciclovir or its metabolite penciclovir, in effective amounts for treatment of an HSV infection in a transplant patient. It would have been a matter of routine optimization to determine optimal effective amounts for standard treatment routes (oral or parenteral), and to optimize variables such as co-administration of a combined formulation or simultaneous or sequential administration of separate formulations. The invention as a whole is seen as prima facie obvious, absent unexpected results.

The following publications are cited as of interest. Boker et al (Transplantation 57:1706-1708, 1994) teaches combination of cyclosporin, an anti-inflammatory amount of prostaglandin, and famciclovir, for treatment of hepatitis B virus infection in a transplant patient. Cirelli et al (Antiviral Research 29:141-151, 1996) reviews the state of the art for famciclovir at the time the invention was made; Cirelli cites several studies

of famciclovir use against hepatitis B virus in transplant patients, and several studies showing effective reduction of HSV recurrence with famciclovir.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 703-308-2926. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

September 24, 2003

Mary E. Mosher
MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600